

Complete Summary

GUIDELINE TITLE

ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty).

BIBLIOGRAPHIC SOURCE(S)

Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun; 37(8):2239i-2239lxvi . [629 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Coronary artery disease, including:

- Asymptomatic or mild angina
- Angina class II-IV or unstable angina
- Acute myocardial infarction
- Ischemia after coronary artery bypass graft

GUIDELINE CATEGORY

Evaluation
 Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Geriatrics
Internal Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To make recommendations regarding the appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

TARGET POPULATION

Patients with coronary artery disease

INTERVENTIONS AND PRACTICES CONSIDERED

Percutaneous Coronary Interventions (PCI)

1. Percutaneous coronary interventions, including percutaneous transluminal coronary angioplasty (PTCA), rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents and other catheter devices
2. Insurance of institutional and operator competency in performing percutaneous coronary interventions (quality assurance programs, high-volume operators in high-volume institutions, availability of onsite cardiac surgical back-up or access to cardiac surgical back-up)

Evaluation

1. Angiographic assessment
2. Use of adjunctive technologies
 - Coronary intravascular ultrasound imaging (IVUS)
 - Measurement of coronary flow velocity and coronary vasodilatory reserve
 - Measurement of coronary artery pressure and fractional flow reserve (FFR)

Note: The following interventions and practices are discussed; however, no specific recommendations are offered:

1. Antiplatelet and antithrombotic therapies in patients undergoing percutaneous coronary intervention
2. Post-percutaneous coronary intervention management
3. Special considerations (for example, management of clinical restenosis, ad hoc angioplasty, percutaneous coronary intervention in the cardiac transplant patients, and restenosis after stent implantation)

MAJOR OUTCOMES CONSIDERED

- Success rates of percutaneous coronary intervention procedures as defined by angiographic (minimum stenosis diameter reduction to <20%), procedural, and clinical criteria (relief of signs and symptoms, rate of restenosis)
- Rates of procedural complications of percutaneous coronary intervention, such as: death, myocardial infarction, emergency coronary artery bypass graft (CABG), stroke, vascular access site complications, and contrast agent nephropathy
- Long-term (5- and 10-year) survival rates and event-free survival rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence:

A: Data derived from multiple randomized clinical trials.

B: Data derived from a single randomized trial or nonrandomized studies.

C: Consensus opinion of experts.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Writing groups were specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered, along with frequency of follow-up and cost-effectiveness.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Experts in the subject under consideration are selected from the American College of Cardiology and the American Heart Association to examine subject-specific data and write guidelines. The process includes additional representatives from other medical specialty groups when appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level of Recommendation: The final recommendations for indications for percutaneous coronary intervention are expressed in the standard American College of Cardiology/American Heart Association format as follows:

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/or efficacy of a procedure.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

COST ANALYSIS

Among all diseases worldwide, ischemic heart disease currently ranks fifth in disability burden, and is projected to rank first by the year 2020. As healthcare delivery systems in countries with established economic markets continue to incorporate new and expensive technologies, the costs of medical care have seemingly escalated beyond the revenue historically allotted to health care. Given

limited healthcare resources, a cost-effectiveness analysis (CEA) is appropriate to evaluate percutaneous coronary revascularization strategies. The results of CEAs for any comparable treatment are reported in terms of the incremental cost per unit of health gained, such as 1 year of life adjusted to perfect health (quality-adjusted life year, QALY) compared to the standard of care. By modeling different treatments, different patient subsets and different levels of disease, a series of cost-effectiveness ratios may be constructed to show the tradeoffs associated with choosing among competing interventions.

While there is no established cost-effectiveness ratio threshold, cost-effectiveness ratios of <\$20,000 per QALY (such as seen in the treatment of severe diastolic hypertension or cholesterol lowering in patients with ischemic heart disease) are considered highly favorable and consistent with well accepted therapies. Incremental cost-effectiveness ratios that range between \$20,000 and \$60,000 per QALY may be viewed as reasonably acceptable cost-effective in most economic market countries, whereas ratios >\$60,000 to \$80,000 may be considered to be too expensive for most healthcare systems. The Committee defines useful and efficacious treatments, in terms of cost-effectiveness, as treatments with acceptable or favorable cost-effectiveness ratios. CEA is not by itself sufficient to incorporate all factors necessary for medical decision making on an individual patient basis, nor is it sufficient enough to dictate the broad allocation of societal resources for health care. Rather, CEA aims to serve mainly as an aid to medical decision making on the basis of comparison with other evaluated therapies.

The results of CEA in the field of percutaneous revascularization for ischemic heart disease have been derived from decision models that incorporate literature-based procedure-related morbidity and mortality, coronary disease related mortality, and estimates of the benefit of selected revascularization procedures. When available, results from randomized trials, (Levels of Evidence A and B), are used to estimate the outcomes of each decision tree branch within the decision-analytical model, for example, using data estimating the restenosis rate following uncomplicated coronary stenting of a single, simple, lesion. CEAs have been used to compare medical therapy with percutaneous transluminal coronary angioplasty (PTCA) with coronary bypass surgery, balloon angioplasty with coronary stenting, and routine coronary angiography following acute MI with symptom-driven coronary angiography.

In patients with severe angina, normal left ventricle (LV) function, and single-vessel disease of the left anterior descending artery, the cost-effectiveness ratio for PTCA, directional coronary atherectomy, or coronary stenting that can be expected to provide greater than 90% success rate with less than 3% major acute complication rate is very favorable (<\$20,000 per QALY) compared to medical therapy. The rating also applies to patients with symptomatic angina or documented ischemia and 2-vessel coronary disease in which percutaneous coronary revascularization can be expected to provide greater than 90% success rate with less than 3% major acute complication rate. In patients with 3-vessel coronary disease who have comorbidities that increase operative risk for coronary artery bypass graft (CABG) surgery, percutaneous coronary interventions (PCI) that is felt to be safe and feasible is reasonably acceptable (\$20,000-\$60,000 per QALY). In patients in the post-MI setting, a strategy of routine, nonsymptom-driven, coronary angiography and PCI performed for critical (>70% diameter

stenosis) culprit coronary lesions amenable to balloon angioplasty or stenting has been proposed to be reasonably cost-effective in many subgroups.

In patients with symptomatic angina or documented ischemia and 3-vessel coronary disease, for which bypass surgery can be expected to provide full revascularization and an acute complication rate of less than 5%, the cost-effectiveness of PCI is not well established. Although PTCA for 2- and 3-vessel coronary disease appears to be as safe, but initially less expensive, than CABG surgery, the costs of PTCA converge towards the higher costs of bypass surgery after 3 to 5 years. Thus, while PTCA or CABG surgery has been shown to be cost-effective when compared to medical therapy, there is no evidence for incremental cost-effectiveness of PTCA over bypass surgery for 2- or 3-vessel coronary disease in patients who are considered good candidates for both procedures. For patients with 1- or 2-vessel coronary disease who are asymptomatic or have only mild angina, without documented left main disease, the estimated cost-effectiveness ratios for PCI are greater than \$80,000 per QALY compared with medical therapy, and are thus considered less favorable.

The initial mean cost of angioplasty was 65% that of surgery, but need for repeat interventions increased medical expenses so that after 5 years the total medical cost of PTCA was 95% that of surgery (\$56,225 vs. \$58,889), a significant difference of \$2,664 ($p = 0.047$). Compared to CABG, PTCA appeared less costly for patients with 2-vessel disease, but not for patients with 3-vessel disease.

Because cost-effectiveness analysis (CEA) research is new in the field of percutaneous coronary intervention, cost-effectiveness analysis results are limited. The Committee underscores the need for cost containment and careful decision making regarding the use of PCI strategies.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed by three official reviewers nominated by the American College of Cardiology (ACC), three official reviewers nominated by the American Heart Association (AHA), the American Heart Association Committee on Diagnostic and Interventional Cardiac Catheterization, the American College of Cardiology Interventional Database Committee, the American College of Cardiology Cath Lab Accreditation Working Group, the American College of Cardiology Cardiac Catheterization Committee, the Society for Cardiac Angiography and Interventions (SCA&I), and 21 outside reviewers nominated by the Writing Committee. This document was approved for publication by the governing bodies of American College of Cardiology and American Heart Association and officially endorsed by the Society of Cardiac Angiography and Interventions.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC)

Levels of recommendation (I-III) and strengths of evidence (A-C) are defined at the end of the Major Recommendation field.

Recommendations for Percutaneous Coronary Intervention Institutional and Operator Volumes at Centers With Onsite Cardiac Surgery

Class I

1. Percutaneous coronary intervention done by operators with acceptable volume (≥ 75) at high-volume centers (>400). (Level of Evidence: B)

Class IIa

1. Percutaneous coronary intervention done by operators with acceptable volume (≥ 75) at low-volume centers (200-400). (Level of Evidence: C)
2. Percutaneous coronary intervention done by low-volume operators (<75) at high-volume centers (>400). Note: Ideally operators with an annual procedure volume <75 should only work at institutions with an activity level of >600 procedures/year.* (Level of Evidence: C)

Class III

1. Percutaneous coronary intervention done by low-volume operators (<75) at low-volume centers (200-400). Note: An institution with a volume <200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer service.* (Level of Evidence: C)

*Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume >150 procedures/year.

Recommendations for Percutaneous Coronary Intervention With and Without On-Site Cardiac Surgery

Class I

1. Patients undergoing elective percutaneous coronary intervention in facilities with on-site cardiac surgery. (Level of Evidence: B)
2. Patients undergoing primary percutaneous coronary intervention in facilities with on-site cardiac surgery. (Level of Evidence: B)

Class IIb

1. Patients undergoing primary percutaneous coronary intervention in facilities without on-site cardiac surgery, but with a proven plan for rapid access (within 1 hour) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with ST-segment elevation myocardial infarction or new left bundle branch block on electrocardiograph, and done in a timely fashion (balloon inflation within 90 ± 30 min of admission) by persons skilled in the procedure (≥ 75 percutaneous coronary interventions/year) and only at facilities performing a minimum of 36 primary percutaneous coronary intervention procedures per year. (Level of Evidence: B)

Class III

1. Patients undergoing elective percutaneous coronary intervention in facilities without on-site cardiac surgery. (Level of Evidence: C)
2. Patients undergoing primary percutaneous coronary intervention in facilities without on-site cardiac surgery and without a proven plan for rapid access (within 1 hour) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer or when performed by lower skilled operators (< 75 percutaneous coronary interventions per year) in a facility performing < 36 primary percutaneous coronary intervention procedures per year. (Level of Evidence: C)

Recommendations for Percutaneous Coronary Intervention in Asymptomatic or Class I Angina Patients

Class I

1. Patients who do not have treated diabetes with asymptomatic ischemia or mild angina with 1 or more significant lesions in 1 or 2 coronary arteries suitable for percutaneous coronary intervention with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a large area of viable myocardium. (Level of Evidence: B)

Class IIa

1. The same clinical and anatomic requirements for Class I, except the myocardial area at risk is of moderate size or the patient has treated diabetes. (Level of Evidence: B)

Class IIb

1. Patients with asymptomatic ischemia or mild angina with ≥ 3 coronary arteries suitable for percutaneous coronary intervention with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend at least a moderate area of viable myocardium. In the physician's judgment, there should be evidence of myocardial ischemia by electrocardiograph exercise testing, stress nuclear imaging, stress echocardiography or ambulatory electrocardiograph monitoring or intracoronary physiologic measurements. (Level of Evidence: B)

Class III

1. Patients with asymptomatic ischemia or mild angina who do not meet the criteria as listed under Class I or Class II and who have:
 - a. Only a small area of viable myocardium at risk
 - b. No objective evidence of ischemia
 - c. Lesions that have a low likelihood of successful dilatation
 - d. Mild symptoms that are unlikely to be due to myocardial ischemia
 - e. Factors associated with increased risk of morbidity or mortality
 - f. Left main disease
 - g. Insignificant disease <50% (Level of Evidence: C)

Recommendations for Patients with Moderate or Severe Symptoms (Angina Class II to IV, Unstable Angina or Non-ST-Elevation Myocardial Infarction) With Single- or Multivessel Coronary Disease on Medical Therapy

Class I

1. Patients with 1 or more significant lesions in 1 or more coronary arteries suitable for percutaneous coronary intervention with a high likelihood of success and low risk of morbidity or mortality. The vessel(s) to be dilated must subtend a moderate or large area of viable myocardium and have high risk. (Level of Evidence: B)

Class IIa

1. Patients with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. (Level of Evidence: C)

Class IIb

1. Patient has 1 or more lesions to be dilated with reduced likelihood of success or the vessel(s) subtend a less than moderate area of viable myocardium. Patients with 2- or 3-vessel disease, with significant proximal left anterior descending coronary artery disease and treated diabetes or abnormal left ventricular function. (Level of Evidence: B)

Class III

1. Patient has no evidence of myocardial injury or ischemia on objective testing and has not had a trial of medical therapy, or has
 - a. Only a small area of myocardium at risk
 - b. All lesions or the culprit lesion to be dilated with morphology with a low likelihood of success
 - c. A high risk of procedure-related morbidity or mortality. (Level of Evidence: C)
2. Patients with insignificant coronary stenosis (e.g., <50% diameter). (Level of Evidence: C)
3. Patients with significant left main coronary artery disease who are candidates for coronary artery bypass graft. (Level of Evidence: B)

Recommendations for Primary Percutaneous Coronary Intervention for Acute Transmural Myocardial Infarction Patients as an Alternative to Thrombolysis

Class I

1. As an alternative to thrombolytic therapy in patients with acute myocardial infarction and ST-segment elevation or new or presumed new left bundle branch block who can undergo angioplasty of the infarct artery ≤ 12 hours from the onset of ischemic symptoms or >12 hours if symptoms persist, if performed in a timely fashion* by individuals skilled in the procedure# and supported by experienced personnel in an appropriate laboratory environment. ** (Level of Evidence: A)
2. In patients who are within 36 hours of an acute ST elevation/Q-wave or new left bundle branch block myocardial infarction who develop cardiogenic shock, are <75 years of age, and revascularization can be performed within 18 hours of the onset of shock by individuals skilled in the procedure# and supported by experienced personnel in an appropriate laboratory environment. ** (Level of Evidence: A)

* Performance standard: balloon inflation within 90 ± 30 min of hospital admission.

Individuals who perform ≥ 75 percutaneous coronary intervention procedures per year.

** Centers that perform >200 percutaneous coronary intervention procedures per year and have cardiac surgical capability.

Class IIa

1. As a reperfusion strategy in candidates who have a contraindication to thrombolytic therapy. (Level of Evidence: C)

Class III

1. Elective percutaneous coronary intervention of a non-infarct-related artery at the time of acute myocardial infarction. (Level of Evidence: C)
2. In patients with acute myocardial infarction who:
 - a. have received fibrinolytic therapy within 12 hours and have no symptoms of myocardial ischemia
 - b. are eligible for thrombolytic therapy and are undergoing primary angioplasty by an inexperienced operator (individual who performs <75 percutaneous coronary intervention procedures per year)
 - c. are beyond 12 hours after onset of symptoms and have no evidence of myocardial ischemia. (Level of Evidence: C)

Recommendations for Percutaneous Coronary Intervention After Thrombolysis

Class I

1. Objective evidence for recurrent infarction or ischemia (rescue percutaneous coronary intervention). (Level of Evidence: B)

Class IIa

1. Cardiogenic shock or hemodynamic instability. (Level of Evidence: B)

Class IIb

1. Recurrent angina without objective evidence of ischemia/infarction. (Level of Evidence: C)
2. Angioplasty of the infarct-related artery stenosis within hours to days (48 hours) following successful thrombolytic therapy in asymptomatic patients without clinical and/or inducible evidence of ischemia. (Level of Evidence: B)

Class III

1. Routine percutaneous coronary intervention within 48 hours following failed thrombolysis. (Level of Evidence: B)
2. Routine percutaneous coronary intervention of the infarct-artery stenosis immediately after thrombolytic therapy. (Level of Evidence: A)

Recommendations for Percutaneous Coronary Intervention During Subsequent Hospital Management After Acute Therapy for Acute Myocardial Infarction Including Primary Percutaneous Coronary Intervention

Class I

1. Spontaneous or provokable myocardial ischemia during recovery from infarction. (Level of Evidence: C)
2. Persistent hemodynamic instability. (Level of Evidence: C)

Class IIa

1. Patients with left ventricular ejection fraction ≤ 0.4 , congestive heart failure, or serious ventricular arrhythmias. (Level of Evidence: C)

Class IIb

1. Coronary angiography and angioplasty for an occluded infarct-related artery in an otherwise stable patient to revascularize that artery (open artery hypothesis). (Level of Evidence: C)
2. All patients after a non-Q-wave myocardial infarction. (Level of Evidence: C)
3. Clinical heart failure during the acute episode, but subsequent demonstration of preserved left ventricular function (left ventricular ejection fraction > 0.4). (Level of Evidence: C)

Class III

1. Percutaneous coronary intervention of the infarct-related artery within 48 to 72 hours after thrombolytic therapy without evidence of spontaneous or provokable ischemia. (Level of Evidence: C)

Recommendations for Percutaneous Coronary Intervention With Prior Coronary Artery Bypass Graft

Class I

1. Patients with early ischemia (usually within 30 days) after coronary artery bypass graft. (Level of Evidence: B)

Class IIa

1. Patients with ischemia occurring 1 to 3 years postoperatively and preserved left ventricular function with discrete lesions in graft conduits. (Level of Evidence: B)
2. Disabling angina secondary to new disease in a native coronary circulation. (If angina is not typical, the objective evidence of ischemia should be obtained.) (Level of Evidence: B)
3. Patients with diseased vein grafts >3 years following coronary artery bypass graft. (Level of Evidence: B)

Class III

1. Percutaneous coronary intervention to chronic total vein graft occlusions. (Level of Evidence: B)
2. Patients with multivessel disease, failure of multiple saphenous vein grafts, and impaired left ventricular function. (Level of Evidence: B)

Recommendations for Coronary Intravascular Ultrasound

Class IIa

1. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent. (Level of Evidence: B)
2. Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (plaque ablation versus repeat balloon expansion). (Level of Evidence: B)
3. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis. (Level of Evidence: C)
4. Assessment of a suboptimal angiographic result following percutaneous coronary intervention. (Level of Evidence: C)
5. Diagnosis and management of coronary disease following cardiac transplantation. (Level of Evidence: C)
6. Establish presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated. (Level of Evidence: C)
7. Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy. (Level of Evidence: B)

Class IIb

1. Determine extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild coronary artery disease on angiography. (Level of Evidence: C)
2. Preinterventional assessment of lesional characteristics and vessel dimensions as a means to select an optimal revascularization device. (Level of Evidence: C)

Class III

1. When angiographic diagnosis is clear and no interventional treatment is planned. (Level of Evidence: C)

Recommendations for Intracoronary Physiologic Measurements (Doppler Ultrasound, Fractional Flow Reserve [FFR])

Class IIa

1. Assessment of the physiological effects of intermediate coronary stenoses (30 to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (Level of Evidence: B)

Class IIb

1. Evaluation of the success of percutaneous coronary revascularization in restoring flow reserve and to predict the risk of restenosis. (Level of Evidence: C)
2. Evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (Level of Evidence: C)

Class III

1. Routine assessment of the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study. (Level of Evidence: C)

Definitions

Levels of Recommendation: The final recommendations for indications for device therapy are expressed in the standard American College of Cardiology/American Heart Association format as follows:

Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- Class II a: Weight of evidence/opinion is in favor of usefulness/efficacy.
- Class II b: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

Levels of Evidence:

A: Data derived from multiple randomized clinical trials.

B: Data derived from a single randomized trial or nonrandomized studies.

C: Consensus opinion of experts.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

POTENTIAL HARMS

Potential procedural complications of percutaneous coronary interventions include: death, myocardial infarction, need for coronary artery bypass graft, cerebral vascular accident/stroke, vascular complications (bleeding, occlusion, dissection, pseudoaneurysm, atrioventricular fistula), renal failure.

Compared with bypass surgery, the disadvantages of percutaneous coronary intervention are early restenosis and the inability to relieve many totally occluded arteries and/or those vessels with extensive atherosclerotic disease.

Subgroups Most Likely to be Harmed:

Procedural complications of percutaneous coronary intervention can be increased in patients with coexistent clinical conditions or other factors. For example, complications occurred in 15.4% of diabetic patients vs. 5.8% of nondiabetic

patients undergoing balloon angioplasty in a multicenter experience. Several studies have reported specific factors associated with increased risk of adverse outcome following balloon angioplasty. These factors include advanced age, female gender, unstable angina, congestive heart failure (CHF), diabetes, and multivessel coronary artery disease.

The clinical and angiographic variables associated with increased mortality from percutaneous coronary interventions include advanced age (age >75 years), female gender, diabetes, prior myocardial infarction, multivessel disease, left main or equivalent coronary disease, a large area of myocardium at risk, pre-existing impairment of left ventricular or renal function, and collateral vessels supplying significant areas of myocardium that originate distal to the segment to be dilated.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These practice guidelines are intended to assist physicians in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the physician and patient in light of all of the circumstances presented by that patient.

Percutaneous coronary intervention is a technique that has been continually refined and modified; hence continued, periodic guideline revision is anticipated. These guidelines are to be viewed as broad recommendations to aid in the appropriate application of percutaneous coronary intervention. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment and knowledge. They are intended for operators who possess the cognitive and technical skills for performing percutaneous coronary interventions and assume that facilities and resources required to properly perform percutaneous coronary interventions are available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

10M DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun; 37(8):2239i-2239lxvi . [629 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun

GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association

SOURCE(S) OF FUNDING

The American College of Cardiology Foundation and the American Heart Association. No outside funding is accepted.

GUIDELINE COMMITTEE

American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Sidney C. Smith, Jr, MD, FACC, Chair; James T. Dove, MD, FACC; Alice K. Jacobs, MD, FACC; J. Ward Kennedy, MD, MACC; Dean Kereiakes, MD, FACC; Morton J. Kern, MD, FACC; Richard E. Kuntz, MD, FACC; Jeffery J. Popma, MD, FACC; Hartzell V. Schaff, MD, FACC; David O. Williams, MD, FACC

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated yearly and as change occur.

ENDORSER(S)

Society for Cardiovascular Angiography and Interventions

GUIDELINE STATUS

This is the current release of the guideline. This guideline revises a previously issued version (Guidelines for percutaneous transluminal coronary angioplasty. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures. J Am Coll Cardiol 1993;22:2033-54).

These guidelines will be reviewed 1 year after publication and yearly thereafter and are considered current unless the Task Force updates or withdraws them from distribution.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American College of Cardiology (ACC) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

Print copies: Available from ACC, Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; (800) 253-4636 (US only). Also available from AHA, Public Information, 7272 Greenville Ave, Dallas TX 75231-4596; Reprint No. 71-0206.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACC/AHA guidelines for percutaneous coronary intervention: executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). (1) J Am Coll Cardiol 2001 Jun 15;37(8):2215-38; (2) Circulation 2001 Jun 19;103(24):3019-41.

Electronic copies: Available from the [American College of Cardiology \(ACC\) Web site](#).

Also available from the [American Heart Association \(AHA\) Web site](#).

Print copies: Available from the American College of Cardiology (ACC), Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; (800) 253-4636 (US only). Also available from AHA, Public Information, 7272 Greenville Ave, Dallas TX 75231-4596; Reprint No. 71-0205.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 17, 2001. The information was verified by the guideline developer on January 18, 2002.

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